High Speed Rotational Atherectomy: Outcome in Calcified and Noncalcified Coronary Artery Lesions

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Objectives. **This study sought to determine the success and complication rates of high speed rotational coronary atherectomy in calcified and noncalcified lesions.**

Background. **Percutaneous transluminal coronary angioplasty and directional coronary atherectomy of calcified lesions are associated with reduced procedural success and increased complications. Rotational atherectomy using the Rotablator catheter abrades noncompliant plaque and may improve outcome in calcified lesions.**

Methods. **Data from the completed Multicenter Rotablator Registry of 2,161 rotational atherectomy procedures in single lesions were analyzed to determine the relative efficacy of rotational atherectomy for 1,078 calcified and 1,083 noncalcified lesions. The power of the study was 0.86 to detect a significant difference in outcome, if the true success rates in the noncalcified and calcified lesions were 96% and 93%, respectively.**

Results. **Patients with calcified lesions were older (mean [±SD] age 66.2 ± 10.3 vs. 60.5 ± 11.0 years, p = 0.0001) than those with noncalcified lesions. Calcified lesions were more frequently new (75% vs. 64%, p = 0.0001), angulated (27% vs. 22%, p = 0.02), eccentric (75% vs. 64%, p = 0.0001) and long (32% vs. 27%, >10 mm in length, p = 0.01). They were also more often complex (57% vs. 46%, p = 0.001) and located in the left anterior descending coronary artery (51% vs. 44%, p = 0.001). Adjunctive coronary angioplasty was used in 82.9% of calcified and 66.9% of noncalcified lesions. Procedural success, defined as <50% residual stenosis without major complication, was achieved in 94.3% of calcified and 95.2% of noncalcified lesions (p = 0.32). Major complication rates were 4.1% in calcified and 3.1% in noncalcified lesions (p = 0.24). Non-Q wave myocardial infarction was documented in 10.0% of calcified and 7.7% of noncalcified lesions (p = 0.054). Mean postprocedural residual stenosis was 21.6 ± 13.9% in calcified and 23.3 ± 15% in noncalcified lesions (p = 0.39).**

Conclusions. **In this review of data from a large multicenter registry, the success rate of rotational atherectomy was not reduced by calcification despite the more frequent complex nature of the calcified lesions. The Rotablator catheter is likely to be the device of choice for percutaneous intervention in calcified lesions, but definitive conclusions await the results of randomized trials.**

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The success and complication rates of percutaneous coronary interventions are dependent on a number of patient- and lesion-specific characteristics. Although the overall success rate of percutaneous coronary balloon angioplasty and directional coronary atherectomy are >90% (1–3), success may be reduced and complications increased in the presence of lesion calcification. Bredlau et al. (4) identified lesion calcification as an independent predictor of major complications after coronary angioplasty, an observation that has been confirmed by others (5,6). The recognition of reduced interventional success in complex lesions has led to the development of alternative modalities of treatment, including high speed rotational atherectomy (7). Preliminary reports (8,9) have suggested an improved success rate in calcified lesions using the Rotablator system (Heart Technology Inc.). We reviewed the data from the Multicenter Rotablator Registry (see Appendix) to determine the relative efficacy of high speed rotational atherectomy in calcified and noncalcified lesions.

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Methods

Patient group. Data from a multicenter registry of 2,953 rotational atherectomy procedures involving 3,717 lesions in 2,700 patients were reviewed. The institutions contributing to this registry are listed in the Appendix, and inclusion and exclusion criteria are presented in Table 1. Patients provided

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Table 1. Inclusion and Exclusion Criteria for the Multicenter Rotablator Registry

Inclusion criteria
Target lesion >70% stenosis
Patient must be candidate for coronary artery bypass surgery
Exclusion criteria
Lesion >25 mm long
Ejection fraction <30%
Unprotected left main coronary artery disease
Patients with occlusion through which a guide wire will not pass
Angiographic evidence of thrombus pretreatment
Severe diffuse three-vessel disease
Extensive dissection within 1 mo of previous coronary angioplasty
Vein graft lesions

informed written consent for the use of an investigational device, and the protocol was approved by the relevant institutional ethics committees. Only procedures involving the treatment of a solitary lesion were included in the analysis so that complications could be assigned to a specific lesion. Of 2,161 procedures in single lesions, 1,078 involved calcified and 1,083 noncalcified lesions.

Procedure. The Rotablator catheter consists of an elliptic, diamond-coated burr connected by a flexible, Teflon-sheathed drive shaft to a gas-driven turbine. This burr rotates at up to 190,000 rpm, abrading atherosclerotic lesions into particles generally <5 μm in diameter (7). The technique used with the Rotablator system has been previously described (10). After pretreatment of patients with aspirin and calcium channel blocking agents, a 9F to 10F sheath was introduced into the femoral artery and the appropriate 9F to 10F guiding catheter used. A temporary pacing wire was inserted when the vessel supplying the atrioventricular (AV) node was to be treated. After the administration of heparin, a specialized 0.009-in. guide wire (Heart Technology, Inc.) was positioned across the target lesion, ensuring that the radiopaque, 0.017-in. tip was free and distal to the segment to be treated. Then a burr (range 1.25 to 2.50 mm) (Rotablator catheter, Heart Technology, Inc.) was used to treat the lesion. Burr size could be subsequently increased or adjunctive coronary angioplasty performed at the operator's discretion. A typical example of a treated calcified lesion is presented in Figure 1. Angiograms were analyzed at the investigating center. Fifteen sites reported either caliper or quantitative angiographic measurements, and five reported visual assessments.

Definitions. *Calcification* was defined as radiopacity at the site of the target lesion, visible on fluoroscopy. The extent of calcification was not graded. Lesions were assessed for the presence of eccentricity, length >10 mm, angulation ≥30°, bifurcation, ostial location and total occlusion. Lesions were considered to be *complex* when they had two or more of these other angiographic features. *Procedural success* was defined as a <50% residual stenosis at the end of the procedure, without in-hospital death, Q wave myocardial infarction or urgent coronary artery bypass surgery. *Non-Q wave myocardial infarction* was diagnosed when there was a two and a half-fold increase in postprocedural creatinine kinase (CK) levels in the absence of new electrocardiographic Q waves.

Statistics. Continuous variables were expressed as mean values ± SD and compared using a two-tailed Student *t* test. Outcomes were expressed as proportions and their variability as 95% confidence intervals. Categoric variables were compared by chi-square analysis. Logistic regression analysis was used to determine the independent effect of variables on outcome. The study had the power of 0.86 to detect a difference in outcomes at the alpha 0.05 level if the success rates in the noncalcified and calcified lesions were 96% and 93%, respectively. All p values are reported; statistical significance was accepted at p ≤ 0.05.

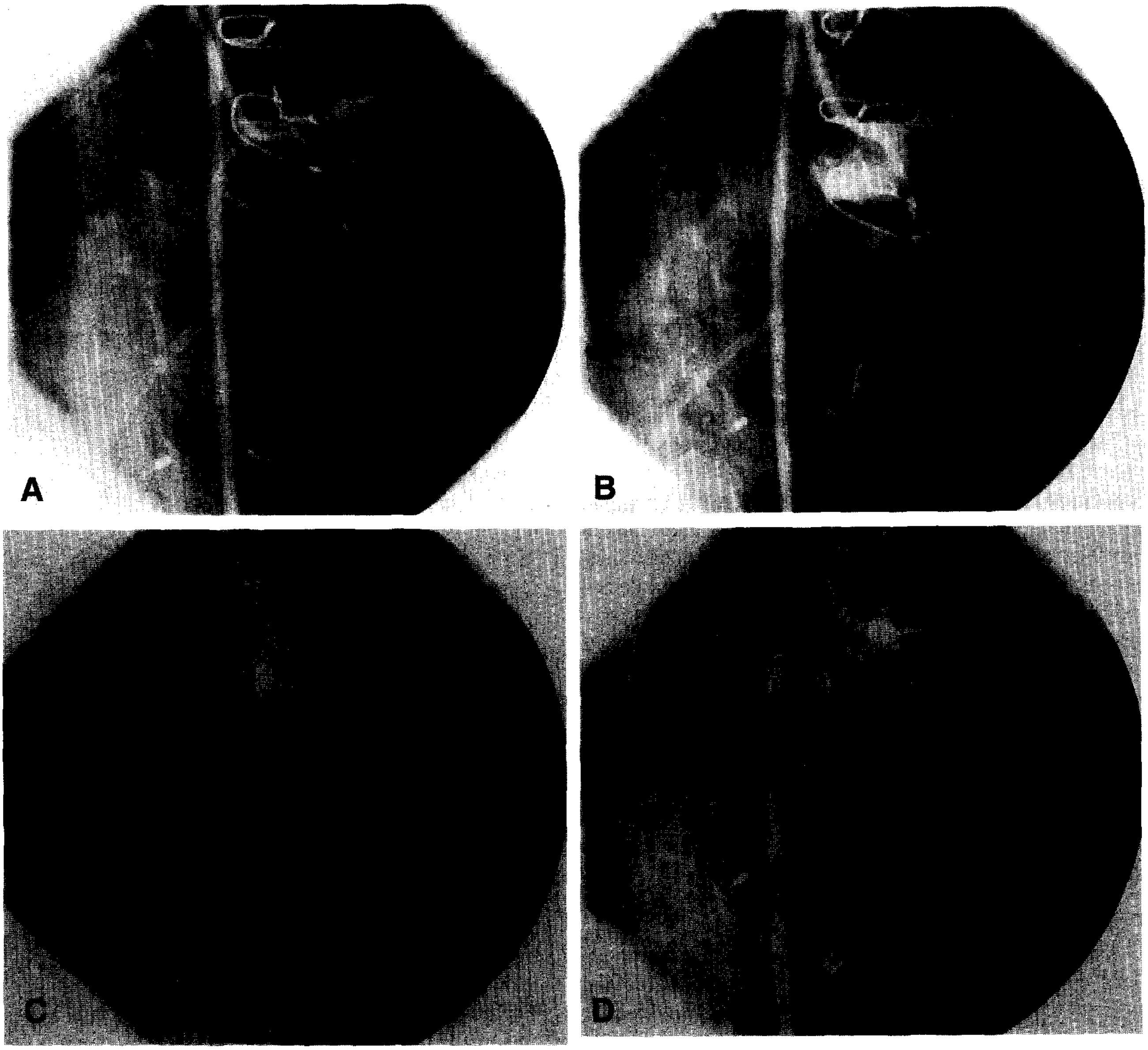
Results

Patient characteristics. Patients with calcified lesions were older, were more often female, had more unstable angina, more frequently had multivessel coronary artery disease and had more previous coronary artery bypass surgery than those with noncalcified lesions. Both groups had a similar incidence of previous myocardial infarction and a similar mean ejection fraction (Table 2).

Lesion characteristics. Mean preprocedural percent stenosis was 82.9 ± 11.7% for calcified and 83.4 ± 11.4% for noncalcified lesions (p = 0.34). Calcified lesions were more frequently new lesions, more often >10 mm in length, more frequently eccentric and more often located in angulated segments than noncalcified lesions. There was no difference in the incidence of ostial lesions, complete occlusions or bifurcation lesions between groups (Table 3). Calcified lesions were more often complex (57% vs. 46%, p = 0.001) (Fig. 2) and more frequently located in the left anterior descending coronary artery (51% vs. 44%) and left main trunk (5% vs. 2%) and less frequently in the right coronary artery (28% vs. 30%) and circumflex artery (16% vs. 23%) (p = 0.001).

Success and complication rates (Table 4). Procedural success rate was not different for calcified (94.3%) and noncalcified lesions (95.2%) (p = 0.32). Mean final burr/artery ratio was 0.70 ± 0.93 for calcified and 0.77 ± 0.15 for noncalcified lesions (p = 0.04). More calcified lesions were treated with post-Rotablator balloon angioplasty to achieve an optimal result than were noncalcified lesions (82.9% vs. 66.9%, p = 0.0001). Balloon angioplasty was performed because the Rotablator failed to reduce the target stenosis to <50% in 13.8% of calcified and 12.3% of noncalcified lesions (p = NS). The remaining 1,618 patients had adjunctive balloon angioplasty to optimize a successful (<50% residual stenosis) result. Procedural success was not reduced in the presence of calcification with increasing lesion complexity (Fig. 3). Mean postprocedure residual stenosis was 21.6 ± 13.9% for calcified and 23.3 ± 15.0% for noncalcified lesions (p = 0.39).

Angiographic complications. The procedure was associated with angiographically apparent coronary dissection in 161 (14.9%) of 1,078 calcified and 122 (11.3%) of 1,083 noncalci-



fied lesions (p = 0.01). Abrupt coronary closure occurred in 42 (3.9%) calcified and 36 (3.3%) noncalcified lesions (p = 0.48). Coronary artery perforation complicated rotational atherectomy in 5 (0.46%) calcified and 11 (1.02%) noncalcified lesions

Figure 1. Moderately calcified midcircumflex lesion in a diffusely diseased circumflex coronary artery (**A**) treated initially with a 1.25-mm Rotablator burr (**B**), then a 1.5-mm burr (**C**) and finally with a 2.5-mm balloon catheter (**D**). Angiograms courtesy of Simon Stertzer, MD.

Table 2. Patient Baseline Characteristics

	Calcified Lesions	Noncalcified Lesions	p Value
Mean age (yr)	66.2 ± 10.3	60.5 ± 11.0	0.0001
Male gender	725/1,078 (67%)	789/1,083 (73%)	0.005
Unstable angina	475/1,063 (45%)	420/1,067 (39%)	0.01
Multivessel disease	660/1,066 (66%)	562/926 (48%)	0.03
Prior CABG	212/1,060 (20%)	173/1,048 (17%)	0.04
Prior MI	410/1,045 (39%)	453/1,053 (43%)	0.08
Mean ejection fraction (%)	55.5 ± 14.1	57.4 ± 12.9	0.82

Data presented are mean value ± SD or number (%) of patients. CABG = coronary artery bypass graft surgery; MI = myocardial infarction.

Table 3. Lesion Characteristics

	Calcified Lesions	Noncalcified Lesions	p Value
Eccentric	799/1,066 (75%)	684/1,068 (64%)	0.0001
New	768/1,027 (75%)	657/1,028 (64%)	0.0001
Length >10 mm	338/1,045 (32%)	275/1,014 (27%)	0.01
Angulated	284/1,039 (27%)	227/1,021 (22%)	0.02
Bifurcation	316/1,039 (30%)	279/1,023 (27%)	0.12
Ostial	180/676 (27%)	131/551 (24%)	0.25
Stenosis >90%*	268/1,078 (25%)	261/1,083 (24%)	0.68
Total occlusion	48/1,078 (4.5%)	53/1,083 (4.9%)	0.63
% stenosis	82.9 ± 11.7	83.4 ± 11.4	0.34

*Includes complete occlusions. Data presented are mean value ± SD or number (%) of lesions.

(p = 0.13). No patients with perforation died, but four with perforated noncalcified lesions required urgent coronary artery bypass surgery.

Clinical complications. The incidence of major complications (death, Q wave myocardial infarction or urgent bypass surgery) was 4.1% in calcified and 3.1% in noncalcified lesions (p = 0.24). Fourteen deaths (1.3%) occurred in the calcified lesion group and five (0.5%) in the noncalcified group (p = 0.04). Age >65 years (p = 0.04) was the only other univariate predictor of death. After controlling for age >65 years, there was no further effect of lesion calcification on death (p = 0.10). There was no difference in the incidence of Q wave myocardial infarction (1.02% vs. 0.46%) or emergency coronary artery bypass surgery (1.76% vs. 2.22%) between groups. The non-Q wave myocardial infarction rate was 10.0% for calcified and 7.7% for noncalcified lesions (p = 0.05).

Discussion

Treatment of calcified lesions. New coronary interventional devices are unlikely to replace balloon angioplasty as the mainstay of percutaneous treatment of coronary artery disease. However, newer devices do provide a different mechanism of lumen expansion, and different mechanical approaches may improve outcome in specific lesion subsets where balloon angioplasty has significant limitations. One of these subsets is calcified lesions. The present study indicates that the likelihood of procedural success with the Rotablator catheter is not reduced by the presence of lesion calcification. The success rate of rotational atherectomy was 94.3% in calcified and 95.2% in noncalcified lesions. A composite end point of death, Q wave myocardial infarction and urgent coronary artery bypass surgery was not more frequent in calcified lesions, but procedure-related mortality was increased. This increased mortality was not significant when corrected for patient age. These results are in contradistinction to the reported reduced success rate of percutaneous coronary balloon angioplasty (1,4,5) and directional atherectomy in calcified lesions (3,11). Bredlau et al. (4) reported that major complications occurred in 8% of lesions with balloon angioplasty, which was significantly greater than the 3.9% major complication rate seen in noncalcified lesions. Myler et al. (1) recently reported success and complication rates with balloon angioplasty. Fewer calcified (91%) than noncalcified lesions (94.8%) were successfully treated, and complications were more common in calcified than noncalcified lesions (i.e., 3.6% vs. 1.3%, respectively). Additionally, 5% of calcified lesions did not respond to balloon angioplasty despite high inflation pressures (≥16 atm). In one report (3) directional coronary atherectomy had only a 70% success rate in the presence of calcification. Ellis et al. (11)

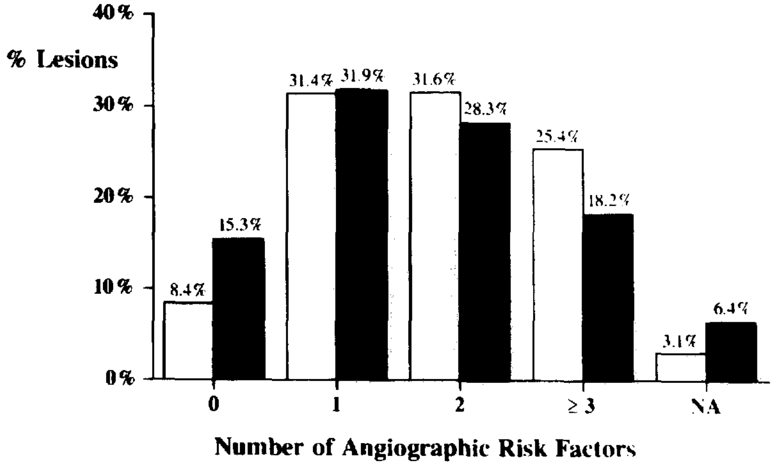


Figure 2. Calcified lesions (**open bars**) more frequently had multiple other angiographic risk factors than noncalcified lesions (**solid bars**) (p = 0.001). NA = not available.

Table 4. Success and Complication Rates (hierarchic)

	Calcified Lesions (n = 1,078)	Noncalcified Lesions (n = 1,083)	p Value
Success	1,016 (94.3%)	1,031 (95.2%)	0.32
Death	14 (1.3%)	5 (0.5%)	0.04
Q wave MI	11 (1.0%)	5 (0.5%)	0.13
CABG	19 (1.7%)	24 (2.2%)	0.45
Non-Q MI	108 (10.0%)	83 (7.7%)	0.054

Data presented are number (%) of patients. Success = <50% residual stenosis without death, Q wave myocardial infarction (MI) or urgent coronary artery bypass surgery (CABG).

reported that the relative risk of atherectomy failure was significantly increased (relative risk 1.98) in calcified lesions.

Mechanism of rotational atherectomy. In contrast, the mechanism of plaque removal with the Rotablator catheter is unique and apparently particularly well suited to calcified lesions. Animal (12), cadaver (13) and human in vivo studies (14) have shown the Rotablator burr selectively removes rigid atherosclerotic lesions, leaving a smooth lumen, especially in heavily calcified lesions. Brogan et al. (15) reported a 90% procedural success rate with the Rotablator system in 41 patients in whom balloon angioplasty had previously been unsuccessful; 74% of these patients had moderate or heavy lesion calcification. However, the approach used with the Rotablator was different for calcified and noncalcified vessels in the present study. The mean burr/artery ratio was smaller for calcified vessels and post-Rotablator balloon angioplasty was used more often in this group. The net result was that the residual stenoses were similar for the two groups. The smaller burr/artery ratios used to treat the calcified lesions may reflect greater operator caution in treating the calcified lesions. These lesions were more frequently complex and >10 mm in length. Despite this more cautious approach, non-Q wave myocardial infarction was more frequent in the calcified lesion group. This finding may reflect the volume of microparticulate debris produced, epicardial or microvascular spasm or other factors not addressed in the present study.

Recent evidence from intravascular ultrasound studies (16) indicates that calcification plays an important role in vessel dissection caused by balloon angioplasty. Percutaneous transluminal coronary angioplasty of calcified lesions often requires high pressure to "crack" the lesion. This radial pressure produces shear forces within the wall that are concentrated at the junction of calcified and noncalcified tissues (17), a frequent site of dissection (16). In the present study, dissection was also more frequent after rotational atherectomy of calcified lesions, although this increased dissection rate did not result in an increased incidence of abrupt vessel closure, urgent coronary artery bypass surgery or Q wave myocardial infarction.

Intracoronary ultrasound may also help identify those patients in whom the Rotablator will be most useful. Further research may indicate that lesions with extensive superficial calcification may be most suitable for treatment with the Rotablator, whereas other devices could be used if the calcification is deep to soft or fibrous plaque. The use of intracoronary ultrasound to guide device selection in individual patients requires further investigation.

Limitations of the study. The present study was not a randomized study of the use of the Rotablator catheter in calcified lesions but a report from a prospective multicenter data base. The degree of calcification was not classified using a qualitative scale, and angiographic characteristics were determined by individual investigators and not a central angiographic core laboratory. Similarly, complications were deter-

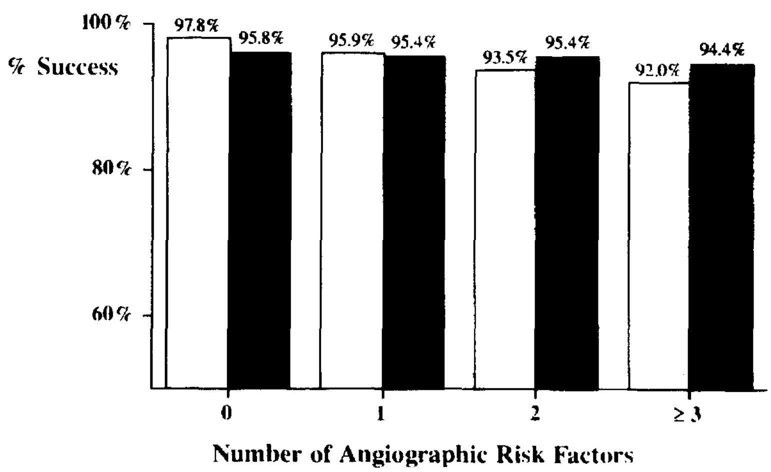


Figure 3. Calcification did not reduce the procedural success rate (% Success) when lesions were analyzed by number of other angiographic risk factors (p = NS, calcified [**open bars**] vs. noncalcified lesions [**solid bars**]).

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mined by the clinical sites, not by an independent review panel. However, all CK levels were reviewed to determine the incidence of non-Q wave myocardial infarction. These data represent a broad multicenter clinical experience with the Rotablator system in a large number of patients and provide the clinician with preliminary information to guide patient selection for use of this recently approved technique.

Summary. The success rate of rotational atherectomy was not reduced by calcification despite the more frequent complex nature of the calcified lesions. Procedural success rates were high and compare favorably with historical control data for other devices. Major procedural complications were not significantly more frequent in calcified lesions. The nonrandomized data in the present study need to be confirmed by a prospective randomized trial. However, the present study indicates that calcified coronary artery lesions can be successfully treated by high speed rotational atherectomy.

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Appendix

Participating Institutions and Co-Investigators for the Multicenter Rotablator Registry

Theodore Bass, *University of Florida Health Sciences Center, Jacksonville, Florida*; Michel Bertrand, *Hopital Cardiologique, Lille, France*; Maurice Buchbinder, *University of California San Diego Medical Center, San Diego, California*; Michael Cleman, *Yale School of Medicine, New Haven, Connecticut*; Barry Cohen, *Newark Beth Israel Medical Center, Newark, New Jersey*; Michael Cowley, *Medical College of Virginia, Richmond, Virginia*; Gerald Dorros, *St. Luke's Medical Center, Milwaukee, Wisconsin*; Raimund Erbel, *Johannes Gutenberg Univarsitat, Mainz, Germany*; Jean Louis Fourrier, *Clinique de la Louviere, Lille, France*: Robert Ginsburg, *Stanford University, Palo Alto, California*; Robert Kipperman and Jospeh Galichia, *Wichita Institute for Medical Research, Wichita, Kansas*: Martin Leon, *Washington Heart Center, Washington, D.C.*; Jean Marco, *Clinique Pasteur, Toulouse, France*; Todd Sherman, *UCLA Medical Center, Los Angeles, California*: Richard Spring, *Washoe Medical Center, Reno, Nevada*: Simon Stertzer, *San Francisco Heart Institute, Daly City, California*; David Warth, *Providence Medical Center, Seattle, Washington*; Patrick Whitlow, *Cleveland Clinic, Cleveland, Ohio*; William O'Neill, *William Beaumont Hospital, Royal Oak, Michigan*; Nadim Zacca, *Methodist Hospital, Houston, Texas*.

References

1. Myler RK, Shaw RE, Stertzer SH, et al. Lesion morphology and coronary angioplasty: current experience and analysis. J Am Coll Cardiol 1992;19:1641–52.
2. Kahn JK, Hartzler GO. Frequency and cause of failure with contemporary balloon angioplasty and implications for new technology. Am J Cardiol 1990;66:858–60.
3. Hinohara T, Rowe MH, Robertson GC, et al. Effect of lesion characteristics on outcome of directional coronary atherectomy. J Am Coll Cardiol 1991;17:1112–20.
4. Bredlau CE, Roubin GS, Leimgruber P, et al. In-hospital morbidity in patients undergoing elective coronary angioplasty. Circulation 1985;72:1044–52.
5. Ellis SG, Vandormael MG, Cowley MJ, et al. Coronary morphologic and clinical determinants of procedural outcome with angioplasty for multivessel disease. Implications for patient selection. Circulation 1990;82:1193–202.
6. Ellis SE, Roubin GS, King SB. Angiographic and clinical predictors of acute closure after native coronary vessel angioplasty. Circulation 1988;77:372–9.
7. Ahn SS, Auth D, Marcus DR, et al. Removal of focal atheromatous lesions by angioscopically guided high speed rotary atherectomy. J Vasc Surg 1988;7:292–300.
8. Gilmore PS, Bass TA, Conetta DA, et al. Single site experience with high-speed coronary rotational atherectomy. Clin Cardiol 1993;16:311–6.
9. Stertzer SH, Rosenblum J, Shaw RE, et al. Coronary rotational ablation: initial experience in 302 procedures. J Am Coll Cardiol 1993;21:287–95.
10. Teirstein PS, Warth DC, Haq N, et al. High speed rotational coronary atherectomy for patients with diffuse coronary artery disease. J Am Coll Cardiol 1991;18:1694–701.
11. Ellis SG, De Cesare NB, Pinkerton CA, et al. Relation of stenosis morphology and clinical presentation to the procedural results of directional coronary atherectomy. Circulation 1991;84:644–53.
12. Hansen DD, Auth DC, Vrako R, et al. Rotational atherectomy in atherosclerotic rabbit iliac arteries. Am Heart J 1988;115:160–5.
13. Ahn SS, Arca MJ, Marcus JR, et al. Histological and morphological effects of rotational atherectomy on human cadaver arteries. Ann Vasc Surg 1990;4:563–9.
14. Mintz GS, Potkin BN, Keren G, et al. Intravascular ultrasound evaluation of the effect of rotational atherectomy in obstructive atherosclerotic coronary artery disease. Circulation 1992;86:1383–93.
15. Brogan WC, Popma JJ, Pichard AD, et al. Rotational coronary atherectomy after unsuccessful coronary balloon angioplasty. Am J Cardiol 1993;71:794–8.
16. Fitzgerald PJ, Ports TA, Yock PG. Contribution of localized calcium deposits to dissection after angioplasty: an observational study using intravascular ultrasound. Circulation 1992;86:64–70.
17. Lee RT, Loree HM, Cheng GC, Lieberman EH, Jaramillo N, Schoen FJ. Computational structural analysis based on intravascular ultrasound imaging before in vitro angioplasty: prediction of plaque fracture locations. J Am Coll Cardiol 1993;21:777–82.